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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,644

03/29/2004

Jill M. Cielo

PC-1485

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23717 7590 12/03/2008  
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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,644	<b>Applicant(s)</b> CIELO, JILL M.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Upon further review and reconsideration, the finality of the office action mailed 10/31/2008 has been withdrawn.

The receipt is acknowledged of applicant's amendment filed 11/10/2008.

Claims 4-12 and 14 have been canceled.

Claims 1-3 and 13 are pending and included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to “composition comprising, among other ingredients, mixed protease” and the mixed protease is “natural enzyme mixture comprises lipase and protease”. The specification gives no guidance to one of ordinary skill in the art regarding “protease or lipase”. The specification does not describe any “protease or lipase”. The terms “protease or lipase” are broad genus and their recitation without partial or complete description of any “protease or lipase” does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The term “protease” includes serine proteases, threonine proteases, cysteine proteases, aspartic proteases, metalloproteases, and glutamic acid proteases, see the provided Wikipedia page. The term “lipase” includes many lipases: digestive lipase, pancreatic lipase, hepatic lipase, lysosomal lipase, hormone sensitive lipase, endothelial lipase, lipoprotein lipase, triglyceride lipase and phospholipase, see the provided Wikipedia page. A genus such as “protease and lipase” can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., *In re Gostelli*, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus. As outlined in *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), a description of a genus can comprise a recitation of structural features common

to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under Section 112, Para.1, by showing the enablement of a representative number of species within the genus. Mere indistinct terms, however, may not suffice to meet the written description requirement.

The instant specification does not describe any "proteases and lipases". Accordingly, the terms "protease and lipase" as used currently by instant claims are deemed so indistinct that fail to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

Additionally, it is not described in the specification which protease and which lipase is suitable to practice the invention and suitable for combination with all the other ingredients without affecting the enzymes activity or the without the other ingredients being affected by the enzyme activity. The terms "protease and lipase" recited without any correlation does not meet the written description requirement for "protease or lipase" as one of ordinary skill in the art could not recognize or understand which proteases or lipases are suitable for practicing the claimed composition from the mere recitation of "protease or lipase". Claims employing terms at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass many proteases and lipases and applicants claimed terms represents only an invitation to experiment regarding possible "protease or lipase".

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the “written description” inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 2003/0007941 ('941), US 2002/0119174 ('174), US 6,030,948 ('948), WO 96/25943 ('943) and US 6,376,557 ('557).

US '941 teaches composition for treating hair loss and useful for treating different types of alopecia, the composition comprising carrier comprising water; up to 11.5% of the composition ammonium lauryl sulfate; 2-4%, sodium laureth sulfate; 2% cocamide MEA; 0.1% sodium chloride; 1-3% cocamidopropyl betaine; 0.5% fragrance (example C, page 16). Additionally, the reference disclosed the topical composition may contain propylene glycol (paragraph 0280), and urea (paragraph 0294).

US '941 does not teach tall oil, EDTA, methyl paraben, propyl paraben, disodium salts of sulfosuccinate, cocoamide DEA, alkyloxypolyethyleneoxyethanol, and sodium sulfate as claimed by claims 1 and 13.

US '174 teaches composition for regulating hair growth comprising pine oil (tall oil), EDTA, methyl paraben, propyl paraben, coconut monethanolamide (cocamide MEA) and coconut diethanolamide (cocoamide DEA), lactamide monethanolamine,

disodium salts of sulfosuccinate and sodium sulfate (paragraphs: 0036, 0084, 0102, 0103, 0112, 0133, 0141, 0234, 0304, 0331, 0336, 0351).

US '948 teaches hair regeneration composition useful for treating alopecia comprising urea gel and alkyloxypolyethyleneoxyethanol (abstract; col.2, lines 47-50; table 4 at col.11).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition to treat hair loss comprising water; ammonium lauryl sulfate; sodium laureth sulfate; cocamide MEA; sodium chloride; cocamidopropyl betaine; propylene glycol, and urea as disclosed by US '941, and add the ingredients disclosed by US '174 comprising pine oil, EDTA, methyl paraben, propyl paraben, lactamide monethanolamine, disodium salts of sulfosuccinate, and sodium sulfate and further add alkyloxypolyethyleneoxyethanol disclosed by US '948. One would have motivated to do so because the references teach composition comprising such ingredients are useful to regulate hair growth and treat alopecia, as desired by US '941. One would reasonably expected formulating composition comprising all the above ingredients disclosed by the three references in one composition, wherein the composition effectively useful to treat hair loss and regeneration and regulate hair growth in person suffering from alopecia.

The references do not teach the exact amounts of some ingredients as instantly claimed. However, the claimed amounts do not impart patentability to the claims, absent evidence to the contrary.



US '941, US '174 and US '948 do not teach enzymes as claimed by claims 1-3, and 13.

WO '943 teaches composition to stimulate hair follicles and hair growth, wherein the composition comprises enzymes trypsin (protease) and dispase (lipase) in effective amounts to enhance the penetration of the individual components in the hair growth composition through intact skin. The amount of enzymes is less than 1% (abstract; page 16, first two paragraphs).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add trypsin and dispase enzymes disclosed by WO '943. One would have been motivated to do so because WO '943 teaches enzymes enhance the penetration of the individual components in the hair growth composition through intact skin. One would reasonably expected formulating composition stimulating hair growth that comprises enzymes that effectively enhance the penetration of the individual components in the hair growth composition through intact skin to achieve enhanced successful hair growth stimulation.

Although the combination of US '941, US '174 and US '948 teaches composition comprising urea, however, the combination does not explicitly teach diazolidinyl urea as claimed by claims 1 and 13.

US '557 teaches hair growth promoter composition useful to treat alopecia and comprising diazolidinyl urea that has effective anti-bacterial and preservative action on the composition (abstract; col.8, lines 3-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hair growth generation composition comprising the ingredients disclosed by the combination of US '941, US '174 and US '948, and further add diazolidinyl urea disclosed by US '557. One would have been motivated to do so because US '557 teaches diazolidinyl urea has effective anti-bacterial and preservative action on the hair growth promoter composition. One would reasonably expected formulating composition to promote hair growth that comprises diazolidinyl urea that provides effective anti-bacterial and preservative action on the composition to achieve stable hair growth composition.

### ***Response to Arguments***

5. Applicant's arguments filed 11/10/2008 have been fully considered but they are not persuasive.

Applicant argues that claims 1 and 13 as amended include a composition that is "consisting of" the claimed ingredients in the claimed amounts, which the applicant has found to be a novel invention for "reducing hair loss and promoting hair life".

In response to this argument, it is argued all the elements of the composition are known in the art for the same purpose as hair composition. Elimination of an element and its function is obvious of the function is not desired. *Ex parte Wu* , 10 USPQ 2031

(Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). The reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). It is further argued that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. See *In re kerkhoven* 205 USPQ 1069, 1072; *In Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80) 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by the cited references that these substances are used in compositions to improve hair conditions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to reduce hair loss and promote hair life. Therefore, the artisan would have been motivated to combine the disclosed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Regarding the claimed amounts, even if the references do not specifically teach adding the ingredients in the amounts claimed by applicant, it is argued that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that where a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection.

In response to this argument, the examiner carefully reviewed the rejection and does not find any reference relied upon that is not included in the statement of the rejection. The examiner relied on US '941, US '174, US '948, WO '943 and US '557, and all of them are positively included in the body of the rejection.

Applicant argues that the mere fact that someone in the art can rearrange parts of a reference device to meet the terms of a claim is not by itself sufficient to support a finding of obviousness. Applicant argues that there is no teaching, nor suggestion for

modifying the references of record to include all the novel features of the amended claims, and no reasonable expectation of success found in the prior art.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have added the ingredients of US '174 and US '948 to composition disclosed by US '941 because both of US '174 and US '948 teaches composition comprising ingredients useful to regulate hair growth and treat alopecia, as desired by US '941. Further, one having ordinary skill in the art would have added enzymes taught by WO '943 because WO '943 teaches that enzymes enhance the penetration of the individual components in the hair growth composition through intact skin. Additionally one having ordinary skill in the art would have replaced urea taught by US '948 by diazolidinyl urea disclosed by US '557 because US '557 teaches diazolidinyl urea has effective anti-bacterial and preservative action on the hair growth promoter composition. Therefore, motivation to combine the references does exist as well as reasonable expectation of success provided by the advantage of each reference.

Applicant argues that the Examiner used Applicant's invention as a template through a hindsight reconstruction of Applicants claims to formulate the rejection.

In response to this argument, it is argued that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that to support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established

functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

IG